K010219

FEB 21 2001

510(k) Summary

Trade Name: **Challenger Direct Composite**

Sponsor: International Dental Research (IDR)
15 rue d"Estrees
75007 Paris
France
Owner/Operator Registration # 9032644

Device Generic Name: Tooth shade resin material

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II (76EBF).

Predicate Devices:
The Challenger Direct Composite material is substantially equivalent to the IDR Cristobal material marketed by, which was cleared for marketing by FDA in K980018.

Product Description:
The Challenger Direct Composite is a photopolymerizing dental restoration product designed for use on all anterior and posterior teeth. The product contains BIS-GMA, UDMA and TEDMA resins.

Indications for Use:
Challenger Direct Composite is a photopolymerizing restoration composite designed for use on anterior or posterior teeth for the following:

Filling and rebuilding work using direct technique;
Restoration of crowned teeth;
Fixation;
Building up occlusions;
Restoration of dental necks;
Deciduous teeth restoration

Safety and Performance:
This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), IDR has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and a description of risk analysis procedure. Validation testing is included in design validation and verification planning, and is documented in the device Design History File.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the IDR Challenger Direct Composite has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2001

Inernational Dental Reseach
C/O Ms. Pamela Papineau
Consultant
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K010219
Trade Name: Challenger Director Composite
Regulatory Class: II
Product Code: EBF
Dated: January 19, 2001
Received: January 24, 2001

Dear Ms. Papineau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010219

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Fixation;
Building up occlusions;
Restoration of dental necks;
Deciduous teeth restoration

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010219

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